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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,763	10/06/2003	Barry M. Yomtov	17509-0072	8563

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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,763	YOMTOV ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *4,8-11,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,12-28 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-1-04,4-26-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 7-22-04, 2-9-05*.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Embodiment I, Figure 2.

Embodiment II, Figures 3–4.

IN ADDITION TO THIS ELECTION OF SPECIES, AN ADDITIONAL SPECIES MUST BE CHOSEN BELOW.

If Embodiment I is chosen, Applicant must choose an electrode species from Embodiment A represented by Claim 4 and Embodiment B represented by Claims 5–6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable and generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Kevin King on Thursday, February 09, 2006 a provisional election was made with traverse to prosecute the invention of Embodiments I and A, claims 1–3, 5–7, 12–28, and 31–35. Affirmation of this election must be made by Applicant in replying to this Office Action. Claims 4, 8–11, and 29–30 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statement filed on 1 March 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the fourth entry of the Non-Patent Literature Documents, Santini, et al., "Microchips as Controlled Drug Delivery Devices," ... was not submitted. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission

of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

5. Claim 6 is objected to because of the following informalities: Claim 6 is written as being dependent on claim 4. In view of the context of claim 4 compared to claim 5, it appears that claim 6 should depend from claim 5. Consequently, Examiner will interpret claim 6 as being dependent from claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1–3, 5–7, 12–22, 23–28, and 31–35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 1, "at least one stimulation electrode" is inferentially included. It cannot be determined if the electrode is being positively recited or functionally recited. To positively claim the element, it is suggested to first positively recite the element. Otherwise functional language such as "for" or "adapted to be" should be used.

In claim 3, "a power source" makes the claim incomplete for not connecting it to another element. The claim is a listing of parts.

In claim 5, "a hermetically sealed encasement" is inferentially included.

In claims 12–16, the phrases "for treating/controlling chronic pain (12), a movement disorder (13), incontinence (14), obesity (15), and seizures (16) in a patient" are vague. It is unclear how these further limit any structure/element of claim 1. It is unclear what element/structure these are directed towards.

Claim 23 recites the limitation "the reservoir" in line 9. There is insufficient antecedent basis for this limitation in the claim. In claim 1, Applicant refers to a plurality of reservoirs not "a reservoir."

In claims 31–35, the phrases "for treating/controlling chronic pain (31), a movement disorder (32), incontinence (33), obesity (34), and seizures (35) in a patient" are vague. It is unclear how these further limit any structure/element of claim 23. There is no positive active method step recitation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1–3, 5–7, 12–16, 18–28, 31–32, and 35 are rejected under 35 U.S.C. 102(b) as anticipated by Thompson, Patent Application Publication U.S. 2002/0111601.

Thompson discloses an implantable drug delivery module (Fig. 1–3) which comprises a plurality of reservoirs (Fig. 6, elements 260 and 262), a release system contained in each of the reservoirs (Figs. 5–6; paragraph [0071]), wherein a release system comprises at least one drug (Fig. 6, elements 264 and 266), and a control means for selectively releasing a pharmaceutically

effective amount of the drug from each of the reservoirs (Figs. 5–6; paragraph [0072]); a neural electrical stimulator (Figs. 1–2) which comprises a signal generator connected to at least one stimulation electrode for operable engagement with a neural tissue of a patient (paragraph [0037], lines 8–12); and at least one microcontroller for controlling operational interaction of a drug delivery module and a neural electrical stimulator (Fig. 5; paragraph [0011], lines 2–5; paragraph [0037], lines 10–13); at least one microcontroller controls both a signal generator and a control means of a drug delivery module (Fig. 5); comprising a power source (paragraph [0037], lines 1–2); a stimulation electrode extends a distance from a hermetically sealed encasement containing a drug delivery module and microcontroller and a flexible catheter connects the stimulation electrode to the encasement (Figs. 1–2; paragraph [0037], lines 10–11); telemetry components in operable communication with a microcontroller (Fig. 5; paragraph [0052], lines 8–10); for treating chronic pain (claims 12 and 31), a movement disorder (claims 13 and 32), incontinence and obesity (claims 14 and 15; Since these claims are intended use, Thompson is capable of being used for treating incontinence and obesity since Thompson's device uses several different biologically-active compounds to administer several different therapies), and controlling seizures (claims 16 and 35) in a patient (paragraph [0064]); a control means for selectively releasing a pharmaceutically effective amount of a drug comprises a reservoir cap positioned over each reservoir and a means for actively disintegrating a reservoir cap (Fig. 6, elements 270 and 272; paragraph [0071], lines 8–10); a reservoir cap is electrically conductive and a means for actively disintegrating a reservoir cap comprises an input lead (wire/conductor/anode) and an output lead (wire/conductor/cathode) each connected to a reservoir cap and a power source for delivering an effective amount of electrical current through

a reservoir cap, via an input lead and output lead, to heat and rupture a reservoir cap to release the drug (Fig. 6; paragraphs [0068]–[0072]); one or more sensors operable to deliver a signal to a microcontroller (Fig. 1, element 70; paragraph [0012]; paragraph [0052], lines 19–22); one or more sensors control release of a drug from a drug delivery module (paragraph [0056], lines 1–5) and control generation of an electrical current from a neural stimulator to neural tissue (paragraph [0057], lines 12–15); a drug is an analgesic, an anti-anxiety agent, an anti-incontinence agent, a skeletal muscle relaxant, an anti-convulsant, or an anti-Parkinson agent (paragraph [0064]).

Regarding claim 23, for the phrase "implanting into the patient the implantable drug delivery module of the medical device of claim 1," it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Additionally, Thompson discloses implanting into a patient an implantable drug delivery module (Figs. 1–2); bringing a stimulator electrode into operable engagement with a neural tissue of a patient (Fig 1; paragraph [0037], lines 8–12); activating a signal generator to deliver electrical stimulation from a stimulator electrode to a neural tissue of a patient (paragraph [0037], lines 8–12); and releasing a drug from a reservoir into a patient (paragraph [0071]); a drug and an electrical neural stimulation are delivered simultaneously (paragraph [0037], lines 8 –13); a drug is delivered intermittently or continuously (paragraph [0011], lines 5–8); an electrical stimulation is delivered intermittently or continuously (paragraph [0011], lines 5–8); a drug is released before an electrical neural stimulation and is effective to reduce a stimulation threshold of a neural tissue (paragraphs [0011], lines 5–9 and

[0038], lines 4–15); release of a drug is alternated with delivery of an electrical stimulation (paragraph [0011], lines 5–9).

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by Thompson, Patent Application Publication U.S. 2002/0111601 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thompson, in view of Santini, Jr. et al., U.S. Patent 5,797,898.

Thompson discloses a drug delivery module comprises a microchip drug delivery device (Fig. 9, elements 360 and 362).

In the alternative for a microchip in claim 17, Thompson does not expressly disclose a drug delivery module comprises a microchip drug delivery device. However, Santini, Jr.

discloses a drug delivery module comprises a microchip drug delivery device (Title of the art) to allow for a device to be small enough to be implantable and to allow the release of a wide variety of molecules (drugs) in either a continuous or pulsatile manner.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a drug delivery module comprises a microchip drug delivery device, as taught by Thompson to allow for a device to be small enough to be implantable and to allow the release of a wide variety of molecules (drugs) in either a continuous or pulsatile manner.

13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson as applied to claims 1 and 23 above, and in view of Mann et al., Patent Application Publication U.S. 2002/0055761.

Thompson does not disclose a medical device for treating incontinence in a patient. However, Mann discloses a medical device for treating incontinence in a patient (paragraph [0002]) to reduce or eliminate the incidence of unintentional episodes of bladder emptying and to improve the long-term health of the urinary system by increasing bladder capacity and thus, the time period between emptying.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a medical device for treating incontinence in a patient, as taught by Mann to improve the health of a patient's urinary system.

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson as applied to claims 1 and 23 above, and in view of Barrett et al., U.S. Patent 6,587,719.

Thompson does not disclose a medical device for treating obesity in a patient. However, Barrett discloses a medical device for treating obesity in a patient (sole Figure; column 8, line 58) to produce a sensation of satiety in the patient to effectively control compulsive overeating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a medical device for treating obesity in a patient, as taught by Barrett to improve a patient's eating habits.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
February 14, 2006
14 February 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/14/6